REMARKS

Reconsideration and reexamination of the subject application are respectfully requested in light of the foregoing amendments and following remarks. Amendments are made without disclaimer of any subject matter and without prejudice to Applicants' right to pursue such subject matter in a continuation application.

1. Status of the Claims

Claims 2-11 and 28 are pending. Claims 1 and 12-27 are cancelled. Claims 2-11 and 28 stand rejected. By entry of the present amendment, claims 3-6 are pending and new claims 29-33 are added. Applicants reserve the right to file a divisional or a continuation on the subject matter of any cancelled claims.

2. Support for the Amendments

The specification is amended to correct an obvious typographical error.

Claims 3-5 are amended to change claim dependence or to clarify the language of the claims.

Claim 29 recites "the elasticity of blood vessels *associated with aging* in an individual." The plain meaning of "to associate" in this context is to accompany as a concomitant. Claim 29 is supported at least by claim 7. The specification particularly supports the concept that reduced blood vessel elasticity is "associated with aging," in the sense that reduced blood vessel elasticity may accompany aging. Support can be found, for example, at page 3, lines 29-34, which discloses the association between aging and a drop in the elasticity of blood vessels. At page 6, lines 14-15, the specification further describes a drop in the elasticity of blood vessels as one "symptom or disease due to aging of the blood vessels." Further, the specification in the Figures and Examples discloses a drop in vessel relaxation rate associated with an experimental group of "old rats." "Effective amount" in claim 29 is supported at least at page 8, lines 4-9; page 17, lines 16-31; and page 18, lines 22-34.

New claims 30 and 31 are supported at least by claim 8. New claim 32 is supported by claim 9. New claim 33 is supported by claim 11. Additional support for the claims is found

throughout the specification. For example, at page 6, lines 14-21, the specification further lists cerebral hemorrhage and arteriosclerosis, e.g., ischemic cardiac disease, as among the "symptoms or diseases due to aging of the blood vessels." Further, the specification discloses that aging is a risk factor for various symptoms and diseases (page 2, line 12) and that the prevalence of certain diseases and symptoms generally is associated with aging (page 1, line 25, through page 2, line 2). In particular, the specification at page 2, lines 34-35 describes these symptoms and diseases as among the "changes along with aging of the blood vessels," i.e., associated with aging.

For all these reasons, the amendments to the claims do not enter impermissible new matter into the application.

3. Acknowledgement of Certified Priority Documents

Applicants note with appreciation the indication that all of the certified priority documents have been received in this matter.

4. Acknowledgement of Information Disclosure Statement

Applicants note with appreciation the acknowledgement and consideration of the Information Disclosure Statement (IDS) filed July 11, 2006. Applicants provide an IDS citing the references made of record in copending Application No. 10/485,458, now US2004/0266874 ("Akimoto"). See M.P.E.P. § 2001.6(b).

5. Objections to the Specification

Abstract

The Office objects to the Abstract as "improperly [implying] that disease states of the circulatory system are always a result of 'aging' of a subject." Applicants traverse the objection. The Abstract complies with all the formal requirements stated in 37 C.F.R. § 1.72(b). Because the Abstract complies with all the relevant formal requirements, the objection is without basis and should be withdrawn. The Office cannot refuse the grant of an application on substantive grounds, where the Office states those grounds in the form of an objection. *See* MPEP § 706.01, "[Rejections] Contrasted With Objections" ("If the form of the claim (as distinguished from its

substance) is improper, an 'objection' is made."). To do so improperly deprives the Board of Patent Appeals and Interferences of jurisdiction to review substantive allegations by the Examiner.

Nevertheless, Applicants amend the Abstract solely to expedite prosecution. Support for the amendment is detailed above. The amendment thus does not enter impermissible new matter in to the application.

Drawings

The Office objects to Figure 1, alleging that a "line appears translated upwards to appear [sic] to give the needed results." Office Action, page 3. This allegation is groundless. Applicants strongly traverse the objection and request that the Office withdraw the objection.

Figure 1 depicts the relationship between acetylcholine concentration and the blood vessel relaxation rate, expressed as a relative percentage, in three groups of Fisher rats. *See, e.g.*, Specification, page 5, lines 29-32; page 22, lines 1-8; page 22, line 19, through page 23, line 7 (results of old rat groups are "compared with young rats"). At a concentration of $1x10^{-9}$ M acetylcholine, the percent blood vessel relaxation rate of the OA Group of rats (—●—) is higher than the percent blood vessel relaxation rate of the YC Group (—Δ—). At a concentration of $1x10^{-6}$ M acetylcholine, it is lower.

Applicants have not translated the relationship for the OA Group or any other group "to give the needed results," as the Examiner alleges. Figure 1 thus does not require correction. If the Office is aware of evidence to the contrary, the Office must make that evidence available on the record. *See* MPEP § 2144.03 (Examiner's affidavit). If not, the Office must withdraw the objection.

6. Objections to the Claims

The Office objects to Claim 7-9 on various substantive grounds. The Office has no authority to object to a claim on substantive grounds. *See* MPEP § 706.01. If the Office believes that a rejection is warranted, the Office must make its supporting facts and evidence available on the record, rather than in the form of unsubstantiated speculation on the nature of the relevant art. *See* MPEP § 2144.03 (Examiner's affidavit). Further, the Office must issue a non-final Office

Action stating statutory grounds for any such rejection to allow Applicants to respond fully and to provide the Board jurisdiction for review. In any event, claims 7-9 are herein canceled without prejudice or disclaimer.

7. Rejection of the Claims under 35 U.S.C. § 112, second paragraph

Claim 3

Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office alleges that "the ratio of the arachidonic acid in the total fatty acids comprising the triglyceride is at least 20%" is indefinite, because the ratio to which the claim refers is unclear. Claim 3 is amended to recite that arachidonic acid comprises at least 20% of the total fatty acids in the triglyceride. The claim is definite, and the rejection should be withdrawn.

Claim 5

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office alleges that the phrase "a triglyceride including at least 5% of a triglyceride with a medium-chain fatty acid bonded to the 1,3-position and with arachidonic acid bonded to the 2-position" is indefinite, because it is unclear in what form the remaining 95% triglycerides have. Applicants traverse the rejection as it applies to claim 5 as currently amended for greater clarity.

A dependent claim further limits the subject matter of the claim on which it depends. *See* 35 U.S.C. § 112, fourth paragraph. Claim 5 depends on claim 29, which recites that the triglyceride has arachidonic acid as a component fatty acid. Claim 5 adds the additional limitation that at least 5% of the same triglycerides have a medium-chain fatty acid bonded to the 1,3-position and an arachidonic acid bonded to the 2-position. By the clear meaning of the claim terms, the other 95% or less of the triglycerides having arachidonic acid as a component fatty acid are not so limited. The Office alleges that the remaining 95% or less triglycerides can have other forms. This is not a reason why the claims would be indefinite. *See In re Gardner*, 427

F.2d 786, 166 U.S.P.Q. 138 (C.C.P.A. 1970) ("Breath is not indefiniteness."). Because the claim is definite, the rejection should be withdrawn.

Claim 8

Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse the rejection.

It is well established that "the definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore* , 439 F.2d 1232, 1235, 169 U.S.P.Q. 236, 238 (C.C.P.A. 1971).

In the present case, the Office alleges that "aging" in indefinite, because it is a relative term for which the specification provides no standard for ascertaining the relevant degree. To the contrary, pages 1-3 of the specification disclose the pertinent state of the art with respect to diseases that are associated with "aging." The definiteness of "aging" in the claims must be ascertained in light of this disclosure. *See Moore*, 439 F.2d at 1235, 169 U.S.P.Q. at 238. The definiteness of aging also must be assessed from the standpoint of the skilled artisan. *See, id.* In this context, Applicants submit Najjar *et al.*, "Aging and the circulatory system," In CARDIOVASCULAR MEDICINE, 3rd ed., Willerson *et al.*, eds., Springer-Verlag, London, United Kingdom, pp. 2439-51 (2007) ("Najjar"), which is attached as **Exhibit 1**. Najjar summarizes his studies at page 2439, 1st col., with the comment that "[t]he incidence and prevalence of cardiovascular diseases increase with advancing age." Najjar does not need to disclose an age cut-off, for example, to convey clearly to the artisan what he means by "advancing age." For these reasons, the artisan would understand that certain symptoms and diseases are more prevalent with advancing age, and thus are associated with aging. Accordingly, the skilled artisan would be sufficiently aware of the meets and bounds of "aging" in the claims. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986) (the claims comply with 35 U.S.C. § 112, second paragraph, if they are as precise as the subject matter permits). The rejection accordingly should be withdrawn.

8. Rejection of the Claims under 35 U.S.C. § 112, first paragraph (written description)

Claims 7-11, and 28 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly inadequately described in the specification. The Office specifically alleges that the term "aging" is "not adequately defined." Applicants traverse the rejection.

The Office alleges: "None of the symptoms or diseases is a *result* of aging, but symptoms and diseases have a greater preponderance to occur in an 'aged' subject." Office Action, page 6 (Emphasis added). The present claims recite "associated with aging," to convey the concept that certain symptoms or diseases are more prevalent with aging. The claims thus do not imply or indicate that aging results in various symptoms or diseases. The rejection accordingly should be withdrawn.

9. Rejection of the Claims under 35 U.S.C. § 112, first paragraph (enablement)

Claims 2-11, and 28 are rejected under 35 U.S.C. § 112, first paragraph, because undue experimentation allegedly would be required to practice the claimed methods. Applicants traverse the rejection.

Factors considered when determining whether the experimentation to practice the claimed invention is "undue" include (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands,* 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

The presently claimed invention is directed to a method of treating various symptoms and diseases in an individual, comprising administering to the individual a composition comprising an effective amount of a triglyceride having arachidonic acid as a component fatty acid, wherein the administration treats the symptom or disease. The specification teaches that "[a]ll compounds having arachidonic acid as a component fatty acid can be utilized." *See, e.g.*, Specification, page 7, lines 19-21. The specification specifically exemplifies the use of a composition including at least 5% of a triglyceride with a medium-chain fatty acid bonded to the 1,3-position and with arachidonic acid bonded to the 2-position. *See e.g.*, Specification,

Examples. The Office provides no reason why other triglycerides with arachidonic acid bound to the 1- or 3- position, for example, would not also be effective. The Office in short provides no evidence, as it must, to substantiate a rejection for non-enablement. *See In re Cortright*, 165 F.3d 1353, 1357, 49 U.S.P.Q.2d 1464 (Fed. Cir. 1999). Accordingly, the enabling teachings of the specification are commensurate with the scope of the presently claimed invention. *See In re Fisher*, 166 U.S.P.Q. 19, 24 (C.C.P.A. 1970).

The specification further provides a routine assay to test compositions comprising an effective amount of a triglyceride having arachidonic acid as a component fatty acid, namely the acetylcholine blood vessel relaxation reaction test. *See, e.g.*, Specification, page 19, line 9, *et seq.* The experimental results obtained using this *in vitro* model system constitute a ***working example*** of the claimed invention.

Efficacy in an *in vitro* model constitutes a working example if that model system "correlates" with a disclosed or claimed method invention. *See* MPEP, § 2164.02, "Working Example." Whether a correlation between an *in vitro* model and a method of treating a disease exists must be determined from the perspective of one skilled in the art. *See id.* In this regard, only a reasonable correlation is required—not a rigorous or an invariable exact correlation. *See id.* (citing *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985)).

Applicants provide evidence on the record that efficacy in the acetylcholine blood vessel relaxation reaction test is understood by the skilled artisan to correlate reasonably with efficacy in a method of treating a drop in vessel elasticity, arteriosclerosis, ischemic cardiac disease, and cerebral hemorrhage, as claimed. Najjar discloses that a drop in the elasticity of blood vessels is associated with aging of blood vessels. *See, e.g.*, Ex. 1, page 2439, 2nd col. Najjar further discloses that this age-associated decline in vessel elasticity correlates with various disease states, including atherosclerosis. *See, e.g.*, Ex. 1, page 2444, Table 115.1. For this reason, an assay that measures the effect of a composition on the elasticity of blood vessels would be expected to yield evidence relevant to the ability of the composition to used in the treatment of the various disease states associated with vessel elasticity.

Zeiher *et al.*, "Endothelium-mediated coronary blood flow modulation in humans," *J. Clin. Invest.* 92: 652-62 (August 1993) ("Zeiher") is attached as **Exhibit 2**. Zeiher discloses

throughout a direct correlation between responsiveness of the coronary microvasculature to acetylcholine in patients with early stages of epicardial atherosclerosis and the expected effectiveness of compositions useful to treat atherosclerosis. *See, e.g.*, Ex. 2, page 658, 1st col. Zeiher demonstrates that a successful result in an acetylcholine blood vessel relaxation reaction test (a/k/a acetylcholine-induced vasorelaxation test) correlates with the expected efficacy of compositions in treating atherosclerosis. *See, e.g.*, Ex. 2, page 658, 2nd col. Zeiher teaches that the test results also correlate with efficacy of treating diseases and symptoms generally associated with the effects of age. *See, e.g.*, Ex. 2, pages 659-60, under the heading "Aging."

Accordingly, the skilled artisan accepts efficacy of a compound in the acetylcholine blood vessel relaxation reaction test as correlating with *in vivo* efficacy of the compound in treating a drop in vessel elasticity, arteriosclerosis, ischemic cardiac disease, and cerebral hemorrhage. For this reason, the examples in the specification constitute a working example of the claimed invention. The experimentation thus required to practice the claimed methods is not undue in nature. Accordingly, the specification enables the claims, and the rejection should be withdrawn.

10. Rejection of the Claims Under 35 U.S.C. § 102

Claims 2-6, 10-11, and 28 are rejected under 35 U.S.C. § 102(e)(1) as allegedly anticipated by U.S. 2004/0266874 A1 ("Akimoto"). Applicants traverse the rejection.

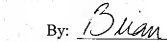
To establish a *prima facie* case of anticipation, a single prior art reference must teach each and every element of the claimed invention, either explicitly or inherently. *Verdegaal Bros. v. Union Oil Co. Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). In the present case, Akimoto does not teach a method of treating a drop of the elasticity of blood vessels in an individual, comprising administering to the individual a composition comprising an effective amount of a triglyceride having arachidonic acid as a component fatty acid, wherein the administration provides said treatment. Because Akimoto does not teach each and every element of the independent claims, Akimoto does not anticipate the claimed invention. The rejection accordingly should be withdrawn.

CONCLUSION

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 50-0573 for any such fees; and Applicants hereby petition for any needed extension of time.

Respectfully submitted,

Date: July 15, 2008

By: 

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